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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/574,712

04/05/2006

Alfio Borghese

X-16289

5430

25885

7590

11/28/2007

ELI LILLY & COMPANY

PATENT DIVISION

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EXAMINER

MABRY, JOHN

ART UNIT

PAPER NUMBER

1625

NOTIFICATION DATE

DELIVERY MODE

11/28/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

Office Action Summary	Application No. 10/574,712	Applicant(s) BORGHESE ET AL.	
	Examiner John Mabry, PhD	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50-70 is/are pending in the application.
- 4a) Of the above claim(s) 52 and 53 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 54-62 is/are allowed.
- 6) ☒ Claim(s) 50, 51 and 63-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner's Response

Applicant's response on November 11, 2007 filed in response to the Office Action dated October 5, 2007 has been received and duly noted. In view of this response, the status of the rejection/objections of record are as follows:

Restriction/Election

Restriction/Election of September 28, 2007 was made final in the Office Action dated October 5, 2007.

Objection

The amendment to modify the title of the application obviates the objection to the title.

35 USC § 102(a)

The 102(a) rejection regarding claims 63-70 has been overcome in view of Applicant's amendments.

35 USC § 103(a)

The 103(a) of record has been withdrawn and a new 102(e) is contained below.

An Action on the merits of claims 50-51 and 63-70 is contained herein below.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 50-51 and 63-70 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Amegadzie et al (WO 2003/091226 A1). Claims 50-51 are drawn to a specific crystalline form and claims 63-70 are drawn to compositions of the corresponding and aforementioned crystalline forms.

Amegadzie et al disclose crystallize compound {2-[1-(3,5-bistrifluoromethylbenzyl)-5-pyridin-4-yl-1H-[1,2,3]triazol-4-yl]-pyridin-3-yl}-(2-chlorophenyl)-methanone and compositions thereof (see page 124, Example 132).

Amegadzie's reference discloses the recrystallized product, {2-[1-(3,5-bistrifluoromethylbenzyl)-5-pyridin-4-yl-1H-[1,2,3]triazol-4-yl]-pyridin-3-yl}-(2-chlorophenyl)-methanone, from ethyl acetate/hexane (see page 124, Example 132, line

14). The instant application claims crystalline form of said product with said data. Thus claims 50-51 and 63-70 are anticipated by Amegadzie et al.

The reference shows the compound, but is silent on the particular crystalline form (polymorph). The compound in said reference will inherently possess the crystalline form (polymorph) as claimed in the instant application. Due to the recrystallization of said product from ethylacetate/hexanes as taught by Amegadzie, the instant claimed crystalline Forms IV and V would inherently exist.

Compositions are taught on page 6, lines 21-24.

MPEP 2112 states:

"Something which is old does not become patentable upon the discovery of a new property

"When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

In this case, the "unknown property" is the particular stereochemistry. This is unknown because the reference is silent on this property. MPEP 2112 goes on to state:

"A rejection under 35 U.S.C. 102/103 can be made when the prior art product seems to be identical except that the prior art is silent as to an inherent characteristic

Where applicant claims a composition of matter in terms of a function, property or characteristic and the composition of matter of the prior art is the same as that of the

claim but and/or Applicant has not clearly distinguished the identity of the composition of matter in the prior art from the composition of matter instantly claimed, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection.”

In another example, certain claims of *Ex parte Raychem Corp.* 25 USPQ2d 1265 required a linearity ratio of less than 1.2. The decision notes that neither reference discloses any values of the linearity ratio. The PTO presented no reasoning as to what the ratio would be expected to be in the references. The Decision states: “However, this does not end the inquiry since, where the Patent and Trademark Office is not equipped to perform the needed testing, it is reasonable to shift the burden of proof to Raychem to establish that (1) the argued difference exists....”

And indeed, there have been a number of cases in which applicants have pointed to silence of the prior art with regard to this or that property: *In re Pearson*, 181 USPQ 641; *In re Zierden* 162 USPQ 102; *In re Lemin*, 140 USPQ 273; *Titanium Metals Corporation of America v. Banner*, 227 USPQ 773; *In re Benner*, 82 USPQ 49, *Zenith Laboratories Inc. v. Bristol-Myers Squibb Co.* 30 USPQ2d 1285, 1288. Going further, if silence about properties of prior art compounds could be relied on, then one could not reject over references with no utility (see *In re Schoenwald*, 22 USPQ2d 1671), since applicants could always insert the utility into the claim as a property.

It is well settled that the PTO can require an applicant to establish that a prior art product does not necessarily possess the characteristics of the claimed product when the prior art and claimed products are identical or substantially identical. An applicant's

burden under these circumstances was described in *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-434 (CCPA 1977) as follows:

Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. . . . Whether the rejection is based on 'inherency' under 35 U.S.C. § 102, or 'prima facie obviousness' under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products (footnote omitted).

Overcoming the rejection is very straightforward. One simply replicates the prior art procedure. If the particular crystalline form (polymorph) does not appear at all in the product, or if on repetition, it sometimes does not appear in the product, then the rejection is overcome. Evidence should be presented in the declaration form.

The Examiner requests a comparison of characteristic data between the compound found in WO 2003/091226 A1 and the claimed products of instant application in order to determine differences and overcome this rejection.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Reasons for Allowance

Claims 54-62 are allowable for the following reasons:

Said claims describe a process of preparing the compound {2-[1-(3,5-bistrifluoromethylbenzyl)-5-pyridin-4-yl-1H-[1,2,3]triazol-4-yl]-pyridin-3-yl}-(2-chlorophenyl)-methanone are different from the prior art of record. Amegadzie et al (WO 2003/091226 A1) describes a process of preparing {2-[1-(3,5-bistrifluoromethylbenzyl)-5-pyridin-4-yl-1H-[1,2,3]triazol-4-yl]-pyridin-3-yl}-(2-chlorophenyl)-methanone, but use a completely different synthetic route to achieve said compound (see page 124, Example 132). Thus, said claims are free of the prior art.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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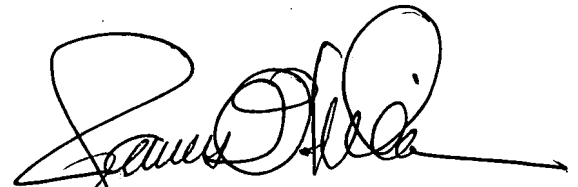
you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Mabry, PhD whose telephone number is (571) 270-1967. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



JM



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